EXHIBIT C

Exhibit B

VIRGINIA EVANS

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA; the States of CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA, WISCONSIN; the DISTRICT OF COLUMBIA; the CITY OF CHICAGO, and the CITY OF NEW YORK, ex rel. OSWALD BILOTTA,	:	Case No. 11 Civ. 0071 (PGG)
Plaintiffs and Relator,	:	
v.	:	
NOVARTIS PHARMACEUTICALS CORPORATION,	:	
Defendant.	:	
UNITED STATES OF AMERICA,	:	
Plaintiff,	:	
v.	:	
NOVARTIS PHARMACEUTICALS CORP.,	:	
Defendant.	:	

VIDEOTAPED DEPOSITION OF VIRGINIA EVANS
New York, New York
January 23, 2018

Reported by:
KATHY S. KLEPFER, RMR, RPR, CRR, CLR
JOB NO. 136542

VIRGINIA EVANS

A. Yes. I have actually published through the American Bar Association Health Law Litigation and Risk Management section a brief article on physician credentialing and the risks that can occur when a physician enters into an agreement with -- with respect to his or her competency and/or other agreement and how that can affect his status under the National Provider Database.

Q. Okay. We've also put before you DX3, which is the expert report of Heidi Sorensen which was prepared in response to your report.

Do you see that?

A. I do.

Q. And have you reviewed that report?

A. I have.

Q. What did you do to prepare for today's deposition?

A. I reviewed the materials that Ms. Sorensen referenced in her report. I reviewed the materials that I referenced in my report. I read both of those reports. I went back and looked at the PhRMA Code and the HHS OIG Guidance for Pharmaceutical Manufacturers. I

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also discussed my testimony with counsel, Ms. Jude.

Q. And when did you do that?

A. I discussed my testimony on Friday for about two hours, three hours, and then again yesterday from 1 till about 6, so about five hours.

Q. Okay. When you say the HHS OIG Guidance, are you referring to the 2003 guidance?

A. Yes, sir. Uh-huh.

Q. And I believe that's in front of you as Defendant's Exhibit 4; is that correct?

A. Yes.

Q. Why don't we open up your report, and to give you a preview of what we're going to do today, for most of the day we're just going to walk through your report, and I'm going to ask you questions. Okay?

A. Okay.

Q. And then when I'm done with that, I'll likely ask you questions about Ms. Sorensen's report. Okay?

A. (Witness nods.)

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Q. On page 1 of your report, we'll start with the Introduction. You say that the U.S. Attorney's Office engaged you to perform a review of and offer an opinion on the effectiveness of NPC's compliance program with respect to certain promotional events.

Do you see that?

A. Yes, sir.

Q. What do you mean by "effectiveness"?

A. When I talk about effectiveness in the context of this report, I'm referring back to the concept of effectiveness as that is described in the Sentencing Guidelines and as is understood in the compliance industry, not only the Sentencing Guidelines, but also the OIG pharma compliance for -- excuse me, compliance guidance for pharma manufacturers as well as the understanding in the industry as to what a compliance -- an effective compliance program is.

Q. As far as understanding in the industry, is there other -- other written documents that you cite other than the OIG guidance and the Sentencing Guidelines that

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could help me understand what "effectiveness" means?

MS. JUDE: Objection to form.

Q. You can answer.

A. Okay. I'm sure that there are other documents that are referenced in these materials. If you can point me to a particular document, I'd be happy to discuss it.

The concept of effectiveness is something that was enumerated, if you will, in the Sentencing Guidelines, outlined in the Sentencing Guidelines, and "effectiveness" has grown to mean since the time of the Sentencing Guidelines, which I think was 1991, to mean the -- whether or not a compliance program does what it's supposed to do in this sense: That it not only sets forth a framework of standards, but those standards are tested and to see whether or not in fact they work. So effectiveness is really a function of is the compliance program working.

Q. Okay. And were you retained by the U.S. Attorney's Office in this matter?

A. Yes, I was.

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Q. And did they approach you about testifying or did you approach them?

A. No, they approached me.

Q. And when they approached you, was your assignment to opine on the effectiveness of the program? Is that what the assignment they gave you?

A. My assignment was to review materials and depositions for a ten-year period with respect to speaker program compliance and then to assess whether or not the compliance program was effective; and if there are certain elements of the compliance program that were not effective, when they became ineffective or when, conversely, they became more effective.

So that was my engagement.

Q. Okay. And the period that you looked at was 2002 to 2011; is that correct?

A. Yes, sir. Although I did go back and look at 2001 because, as I understood it, the compliance guidance, such as there was at Novartis in that -- Novartis Pharmaceuticals in that period dated back to 2001.

Q. And you recognized earlier that the --

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the guidance about what it means to be effective has evolved over time; is that correct?

MS. JUDE: Objection. Misstates testimony.

Q. Is that correct?

A. I can answer?

MS. JUDE: You can answer, yes.

A. Has it evolved over time? No, I don't -- I think that it's inaccurate to say that it has -- it was not present at the beginning. The whole idea of having a compliance program -- and by the "beginning," I mean the beginning of this particular time period, which we'll call the review period -- I think the question of whether or not a compliance program was effective is something that was there from the outset. Because if the compliance program is not effective, there's really no methodology or way to reduce risk within the organization and reduce the risk of misconduct or violations of law or regulations.

So effectiveness not only goes to preventing, detecting, and ameliorating any violations of law, regulations, but also any

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violations of the company's own policy.

So I don't think that it's fair to say that there was no effectiveness in the beginning and it evolved over time. I think that, over the time period, the review period, the companies became more aware of what the government would be expecting in order for there to be an effective compliance program.

Q. Okay. I mean, the word "evolved" is a word I believe you used.

A. Right.

Q. So you're saying that, as time progressed, companies became more aware of what they had to do in order for their program to be effective?

A. Yes; I think that they did -- they became more aware of particular instances of misconduct that were getting other companies in the industry into trouble, and that provided information about -- which one would hope would inform the compliance program.

So if you know that a particular company has gotten in trouble for speaker programs where there are speakers being paid who

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don't show up, let's say, you would want to go back as part of your understanding of what was going on in the pharmaceutical industry as well as the compliance industry and take a look to make sure that that's not happening in your own company.

Q. And --

A. So --

Q. I'm sorry.

A. -- I guess in that sense, you could say that your understanding of what would make an effective speaker program, compliance program would evolve, yeah.

Q. And when was the first published settlement involving a pharmaceutical company relating to speaker programs?

A. I don't know the answer to that question, and but I know that pharmaceutical companies were under investigation, and that was public record back in the late 1990s and as early as 2001.

Q. That related to speaker programs?

A. To speaker programs, yes, or actually, if you -- if you confine the response to speaker

programs, that might be misleading, because speaker programs are any sort of -- fall into the general consulting arrangement that a pharmaceutical company would have with a healthcare professional.

So any sort of benefit being conferred upon the healthcare professional is being reviewed especially in the area of pharmaceutical manufacturers pretty early on. I would say 1990s to, you know, certainly 2001.

Q. And do you know what companies were under investigation that was public, a matter of public record?

A. Well, I don't -- I don't know that I could remember them offhand. I think Novartis' own materials referenced early on several companies that were either under investigation, in the process of entering into settlements, or were examples that management used to explain what the potential risks and liabilities could be.

Q. So one thing that I noticed a distinction between your report and Ms. Sorensen's report is that she relies very

heavily on settlements in these cases, and I don't believe you reference them.

Can you explain why you don't reference them?

A. Well, for two reasons. Basically, I thought it was important to review Novartis' own materials and to determine, in the context of whether or not their speaker program compliance efforts were effective, to go back and look at what they were saying about their own organization.

And I did not rely so heavily on settlements unless -- or did not really refer to settlements unless Novartis referenced them themselves, and that was because it seemed to me that it would be maybe unfair to tag them with knowledge about the particulars of a settlement in a case that they were not involved with. So unless it was something that Novartis referenced, I did not find that -- those settlements to be particularly relevant.

Now, the second reason that I didn't, as Ms. Sorensen did in her report, go through and itemize all of the different settlements and

CIAs is because it's my belief that those are fact-specific to those particular companies, and although CIA can be used as sort of information that can then be folded into a compliance program to give guidance and direction as to what things maybe the company should be looking for, each CIA stands or falls on its own and is the result of a particular settlement with a particular company involving particular facts, and you can see that.

Some of them involve, you know, focus arrangement databases. In some CIAs they call it something different. There was a time period when some CIAs, especially in the pharmaceutical manufacturers world, were requiring compliance experts to help the board. That's no longer the case.

So I see each of the CIAs as being specific to that particular settlement.

Q. But when you measure -- when you measure the effectiveness of Novartis' compliance program, you had to measure it against a standard, correct?

A. Yes.

Q. And so are you saying that CIAs and the requirements of CIAs did not inform that standard because you don't refer to them in your report?

A. No, I'm not saying that at all, and I think the CIAs can be used as guidance. I think that the idea that if something is not articulated in a specific CIA which involves a third party and the government and a different set of facts, it doesn't necessarily mean that you -- you are okay, you don't have to do that until -- a particular item until there's a CIA about it.

So I would go back and say that the standards are really found in the Anti-Kickbacks Statute and the False Claims Act and the Sentencing Guidelines and the PhRMA Code and Pharma Guidance, HHS OIG 2003 Guidance for Pharmaceutical Manufacturers.

Q. So --

A. So the CIAs might inform your program, it might be a great idea to take a look at a CIA and say, wow, that's something that we could do internally here and prevent further misconduct

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or what we perceive to be a risk of fraud waste or abuse, but there's nothing saying that you have to follow what a CIA says.

Q. Okay. So, in measuring the effectiveness of this compliance program, you measured it against the sources that you just listed for me: The OIG Guidance, the PhRMA Code, the Anti-Kickback Statute, the False Claims Act, maybe. I didn't --

A. False Claims Act.

Q. I don't know if there are any others.

A. FDA standards in terms of what they require healthcare providers to explain when they are being engaged as consultants or speakers. They require certain information be conveyed to audiences. So I looked at that as well.

Q. Let me ask you. I don't recall seeing a citation to FDA guidance in your report, but there are 423 footnotes, so I may have missed one.

A. Yes.

Q. Did you cite to FDA guidance that I should look at?

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A. Yes, I believe I did. And in fact, I think the PhRMA Code actually refers back to FDA, and certainly Novartis' own policies refer back to FDA requirements that, you know, a speaker should provide a fair, balance and...

Q. Got it.

A. Yes.

Q. So we're, unfortunately, we're still on the first paragraph of your report.

A. I'm sorry.

Q. No. No. No. That's fine. We have the whole day.

But you were asked to offer an opinion on the effectiveness of the compliance program, and what -- is it fair to say that your opinion is that Novartis' compliance program during this period was not effective?

MS. JUDE: Objection to form.

A. My -- no, my opinion would be that, with respect to speaker programs, speaker program compliance, Novartis' compliance -- speaker program compliance efforts were not effective until about September of 2010.

Q. Okay. And do you have an

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understanding of how that conclusion bears on Novartis' liability in this case?

A. I really did not consider Novartis' liability, or other than briefly reading the complaint, I did not really consider the, if you will, the ultimate conclusion of this civil matter. I was specifically looking at speaker program compliance and whether or not they were effective, as that is -- term is understood in HHS OIG Guidance and...

Q. Are you aware of any case where the liability of a pharmaceutical company in a False Claims Act case relies at all on whether the compliance program was or was not effective?

A. No. My understanding -- no, I am not aware of any particular pharmaceutical case where the ultimate legal conclusion of the case turned on whether or not the compliance program was effective.

I am aware from my time as an assistant U.S. attorney and as chief of the Civil Division that an effective compliance program can be used to show that an organization is less culpable than it might otherwise appear

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under the Sentencing Guidelines, and that can affect HHS's interest in entering into, in the civil realm, in entering into an agreement with them.

If there is a good compliance program in place, HHS will sometimes allow companies to use their own compliance measures. For example, might not -- HHS might not wish to have an IRO involved if the company's got a good compliance program.

So, but whether or not a company has an effective compliance program I see directly relates to its risks that it will be found culpable and, you know, to what degree it was able to address those risks in a manner that was meaningful in both the civil and criminal context.

Q. Okay. And that's in the -- when you say "culpable," you're referring to a decision that the prosecutor will make as to whether to bring an enforcement action?

A. Yes; I think that the Sentencing Guidelines are the basis of the seven elements that later were used when the HHS OIG

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Pharmaceutical Guidance was drafted.

Q. Okay.

MS. JUDE: I just want to put an objection on the record to the extent that this is using Ms. Evans' expertise in this case to try to prove that certain elements of the case are not met.

I mean, she is a lawyer so obviously she can answer these questions. I don't think I need to make them as to form on the record, but she's here purely to offer an opinion about compliance and not about --

MR. GRUENSTEIN: I understand that.

MS. JUDE: -- this case.

MR. GRUENSTEIN: I understand that.

BY MR. GRUENSTEIN:

Q. I want to ask a question that I may not have asked clearly before about your methodology of determining whether a company has an effective compliance program.

I assume you've considered other companies and whether other companies have effective compliance programs?

A. Yes, I have.

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Q. And what is your methodology for that consideration?

A. Well, one of the first things that I would do -- that I do is to take a look at the policies and procedures. The very first element of the -- of an effective compliance program, the first element that's enumerated, I would take a look at those.

It would be my practice then, if there were no depositions, to interview individuals in the organization. If there is -- if that's not an option, the next thing I would do is look at statements from the individuals, and based upon those statements, I would then seek to review documents. And those could be e-mails, they could be training materials, the documents could be financial analyses, complaints, responses to the hotline, investigations, and then any remediations that occurred as a result of those complaints and look to determine whether or not the compliance program has an internal ability to use information gleaned from all of these sources in statements about risk, documents, materials, e-mails, complaints, investigations,

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take all of that information and wind it back into their compliance policies and training and education so that you have some ability to state with confidence that there was a problem, the problem -- a compliance problem, the problem was reviewed, corrective action was drafted, and then a testing after the corrective action was determined and implemented to see if it's working, basically.

Q. So I want to take you out of the context where you're doing that review and litigation as an expert witness.

A. Okay.

Q. Because I assume as a consultant you do this analysis for companies?

A. That's correct.

Q. Okay. And when you do that analysis, you typically will interview people?

A. That's correct.

Q. And presumably you interview key people at the company who deal with the compliance program, correct?

A. Yes.

Q. So, for example, you would interview

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the chief compliance officer?

A. That would -- yes, uh-huh.

Q. And you interview other people in the Compliance Department?

A. Yes.

Q. You interview people in Internal Audit?

A. Sometimes, yes.

Q. And you interview people in Human Resources, perhaps?

A. Sometimes, yes. It really depends on whether or not the compliance program touches those areas, and sometimes it does and sometimes it doesn't. That would be true of both Internal Audit and HR.

Q. And there may be other departments that you would say touch on compliance like, for example, Legal, Finance, maybe others, correct?

A. That's correct.

Q. And there may be times where for you to do a thorough review of a compliance program you have to interview dozens of people, correct?

A. That's correct.

Q. And you review -- you ask -- I'm

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sorry. Let me strike that.

You ask those people to provide you with all relevant policies, correct?

A. Yes.

Q. And then you review those policies thoroughly, correct?

A. Yes. Try to.

Q. And you ask for documentation of instances where there were violations of the policies, correct?

A. Sometimes, yes. Uh-huh.

Q. And you review the investigation reports, if there are investigation reports?

A. Yes.

Q. And that all informs your decision as to whether the company is or is not effective, correct?

A. It helps to -- helps me to come to a conclusion as to whether or not it -- the compliance program is working, yeah.

Q. Okay. Do you ever take proactive steps like issuing a survey to employees?

A. Yes, that is something that I have been involved in with other organizations in the

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past, uh-huh.

Q. And is that helpful for you to determine whether there is a culture of compliance at the company?

A. Yes.

Q. And whether there's a culture of compliance at the company is certainly something that you consider when you're considering whether there is an overall effective compliance program?

A. Yes, that is something that, although culture of compliance is kind of difficult to -- to describe, you know, you --

Q. You know it when you see it?

A. You know it when you see it.

Q. Okay. I feel that way about a lot of the --

A. Right.

Q. -- a lot of the factors that are involved.

And when companies ask you to review their compliance program, at the end of the day, you give them suggestions for improvement?

A. Yes. Yes. Or I may suggest to them

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that they need to do a deeper dive into particular areas because there is apparent risk.

Q. And that itself is a suggestion for improvement?

A. Yes, sir. Uh-huh.

Q. And do you ever say to a company, "Your compliance program is effective. There's nothing more that you need to do"?

A. I have been involved with companies that have excellent compliance programs that are effective, that need very little adjustment.

Q. Okay. Unfortunately, those companies never need to hire me because they never get into any trouble, so I haven't encountered them, but okay.

But it's fair to say that you also have had clients -- I'm talking about consulting clients, not legal clients -- I don't want to tread on the privilege -- but you have had clients where you would conclude that they had effective compliance programs, but there was still room for improvement?

A. That's correct.

Q. And then you've had other clients

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that -- well, let me ask you, have you had other clients where you have reached the conclusion you have an ineffective compliance program?

A. Absolutely.

Q. Okay. And you've given them room for improvement -- you have given them ideas for improvement?

A. Yes, I have.

Q. So it's possible that an effective compliance program has room for improvement as well as an ineffective compliance program, correct?

A. That is possible.

MS. JUDE: Object to the form.

THE WITNESS: I'm sorry.

MS. JUDE: Objection to form.

THE WITNESS: That is possible.

BY MR. GRUENSTEIN:

Q. Of course, the ineffective program has more room for improvement --

A. Yes.

Q. -- than the effective, correct?

A. Yes.

Q. How do you draw the line between an

A. Right, I think that --
Q. You were your own right-hand man?
A. I think that there's a -- that's an error. It should be back one year there.
Q. That's fine.
During those cases, did you litigate any False Claims Act cases?
A. Yes, we did.
Q. Against who?
A. I'm sorry?
Q. Against who?
A. I believe that Serono was -- I supervised the assistant who was handling that case, Serono, in the District of Maryland. I had a number of different healthcare fraud cases that ended up settling out in that district.
I'd have to -- I can't remember the names of them off the top of my head, but there were...
Q. Did any of them involve promotional practices or speaker programs, to your recollection?
A. Well, Serono did. I'm just trying to think. None of them involved speaker programs

per se, but some of them involved benefits to physicians, yeah.
Q. You then worked at KPMG --
A. Right.
Q. -- for a few years, and it says in the first bullet that you did work for pharmaceutical companies. That's in your list?
A. Yes.
Q. Approximately how many pharmaceutical companies did you work for?
A. At least three that I can recall at this point.
Q. And did you provide guidance for them on speaker programs?
A. Yes, and as well as serving as the Independent Review Organization, reviewing their compliance with their corporate integrity agreements, which involved benefits to physicians. If not speaker programs, then other benefits involving promotions, so...
Q. And who were you the IRO for?
A. I was the I- -- I was involved in the IRO with -- I don't know if I'm allowed to disclose this.

MS. JUDE: Yes, I don't know what your confidentiality obligations are, so if you want her to check on that --
THE WITNESS: Right.
MS. JUDE: -- and get back to you, or if there's a way to ask a -- ask it so you can get what you're looking for without the actual name, we can do that.
BY MR. GRUENSTEIN:
Q. The company that you were the IRO for was a pharmaceutical company?
A. There were a number of them. One was a major pharmaceutical retailer. One was a pharmaceutical wholesaler. One was a hospital system. And this would go into my time at Daylight as well. One was an international, large international pharmaceutical company. One was a generic -- I was not an IRO. I drafted the compliance policies for a generic pharmaceutical company, drafted the compliance policies for physician practices and organizations for a number of hospitals and healthcare systems and did compliance reviews of other entities as well.

Q. Other pharmaceutical companies?
A. I'm trying to think if there were any other pharmaceutical companies. There were at least three, so...
Q. And did those pharmaceutical companies, including the generic one that you mentioned, did they do speaker programs?
A. One of them did, yeah, uh-huh.
Q. And can you say which one that is?
A. No, I can't. I don't think it would be appropriate.
Q. And you gave them advice on their speaker program compliance?
A. We gave them advice -- I gave them advice as a compliance expert working with the board and helping the board certify that it had reviewed the compliance policies and programs, very similar to Novartis' corporate integrity agreement that -- so the board could certify and management could certify and the compliance officer could certify that they had reviewed the compliance program and that the compliance program was effective.
Q. And was there a term in that CIA that

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A. Yes, sir, although I believe that other folks participated in the policy drafting later on. By that I would say after 2005, and I don't know how -- how many years into or past 2009, 2010 he remained in the policy-making position.

Q. So if Marty and others thought that these policies were not ambiguous, but then the people you cite thought that the policies were ambiguous, why do you rely on those people and not on Marty?

MS. JUDE: Objection to form.

A. Because when looking at the effectiveness of the policies, it was apparent to me based on subsequent e-mails and other deposition testimony that the sales reps were having a difficult time understanding what was meant by some of the policies.

So they had a difficult time understanding what was meant by "occasional" and an "occasional meal." They had a difficult time understanding who was a legitimate attendee, for example, so -- and then very simple policies like the gifts policy. No gifts? Some gifts?

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Gifts under $100? There were varying interpretations of when it was appropriate to provide gifts, and there were many occasions that I saw in the materials where Mr. Putenis even deferred to Sales and said, you know, let's let Sales make that determination.

Q. You didn't review any depositions of sales reps, did you?

A. I did not.

Q. And if there were depositions of sales reps where they gave the proper interpretation of these policies, how would that influence your analysis, if at all?

MS. JUDE: Objection to form.

A. In my opinion, based upon the policies that I reviewed and the information that the compliance folks had at the time and were discussing and were discussing with senior management, I think that the policies were inadequate, as Mr. Hollasch said. I think that they could have been clearer.

Q. And how does Mr. Hollasch's opinion inform your opinion?

A. At one point, they were talking about

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coming up with more specific modest meal policies, and Mr. Hollasch in an e-mail, fairly late in the review period, maybe it was 2009, said let's push off this modest meal policy effort because the policies that we have now are clearly inadequate.

And that's someone at the time on the scene who's writing about attempting to address a problem that he was aware of because of the earlier internal audit issues that occurred during the 2008 field audit.

So, yeah, I -- at that point in time, that slice in time, it looked to me like the compliance officers were having difficulty getting the sales reps to comprehend the policies.

Q. Okay.

A. And maybe that's because the policies were not very clear.

Q. As a -- as a compliance consultant, you are involved in helping companies draft their policies, correct?

A. Yes, sir.

Q. And it's certainly the case that a

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policy cannot prescribe what an employee should do in every situation; some amount is left to the discretion of the employee, correct?

A. That's generally true unless you have an instance where you know that you're putting individuals who are -- are going to be conflicted because of their inherent role in a position where they're making decisions, and what -- it is often helpful in those circumstances to give a couple of examples or to further define what is meant by "occasional."

Q. Okay. So, in the last sentence of the paragraph, you say, which I think is consistent with what you just said, "In general, leaving room for subjective interpretation of policies designed to prevent fraud is antithetical to an effective compliance program particularly where interpretation is in the hands of sales reps or managers who are compensated based on sales or business goals, and thus are incentivized to interpret policies in a sales-friendly manner."

Correct?

A. That's correct.

Q. And is that principle contained in any

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written guidance that was available during the review period?

MS. JUDE: Objection to form.

Q. Yes or no? That you're aware of.

MS. JUDE: Same objection.

A. Word-for-word --

I'm sorry. Go ahead.

MS. JUDE: Same objection.

A. Word-for-word, it is not -- I don't know that it is in any compliance guidance, but there certainly is a reference in the 2003 HHS OIG Guidance about sales reps being incentivized through their compensation methodology to perform in a particular way, and I think that this would fall under that general risk, so...

Q. Let's look at the next paragraph.

"Minimum Number of Legitimate Attendees." This is a -- this is one of the examples of ambiguity; is that correct?

A. Yes. Uh-huh.

Q. And is this something that the government pointed you to or that you identified on your own?

A. I'm sorry, go ahead.

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MS. JUDE: Objection as to the -- as to the extent to which that's going to reveal attorney information, privileged information under Rule 26.

THE WITNESS: And I -- I actually came upon the number of attendees kind of backwards. I started out, you know, there was no reference in the original HH -- I'm sorry, Healthcare Compliance Guidance about the number of attendees, I think, or there was discussion about that there was no -- in the depositions there was no number, magic number, until I believe it was Mr. Putenis's first set of compliance guidelines, or maybe it was the -- the early -- it was the earliest guidelines, I think, in 2003 maybe that came up with the number it's got to be three or more.

And from there, once I understood that there's got to be three or more healthcare professionals in attendance, I went to what does that mean? Prescribers? Legitimate attendees? And that's when I found the reference to legitimate attendees in

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Novartis' own materials. So they talk about that --

Q. In the first sentence --

A. -- term.

Q. -- you say, "The number of legitimate attendees (i.e., permitted audience members) at Speaker Programs is relevant to AKS risk."

A. Right.

Q. How is it relevant to AKS risk?

A. Well, if there are no attendees and you're paying the speakers, then you're basically paying the speaker for providing a service which is -- has no business purpose or necessity, and therefore, it is -- it's a remuneration to the speaker or benefit to the speaker that may violate the Anti-Kickback Statute.

There is no business reason for it. He's not providing medical or scientific information to healthcare providers or others, not -- you know, so there's no -- there's no meaning for it.

The -- if you have three or less, then I think you raise that risk. It's on that

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continuum three or -- fewer healthcare providers in attendance makes it look like, you know, you're still just paying the provider -- speaker provider for really minimal services.

So that's why I think it becomes important. It goes to whether or not there's a potential violation, the Anti-Kickback Statute.

Q. Okay. So in the companies that you consult with, how many of them would you say you're familiar with their speaker program policies?

A. At least two.

Q. Okay.

A. Uh-huh.

Q. And do those two, are you able to name them here?

A. No. Huh-uh.

Q. And those two, just so I'm clear, those are two -- those are not two current clients? Because I think you said you don't have any pharma clients.

A. That's correct.

Q. Those two clients, did they have policies on the number of legitimate attendees

at speaker programs to your recollection?
A. I know that one did. I don't know about the other ones.
Q. Do you remember what the number was with that one?
A. No, I don't.
Q. Okay. Do you think it was higher than three, or you don't recall?
A. I don't recall.
Q. And was there any -- is there any guidance that you can point to that says that the number of legitimate attendees is relevant to AKS risk?
MS. JUDE: Objection to form.
A. Once again, I'd go back to the 2003 pharma.
Q. OIG?
A. OIG Guidance. And also, there was internal information and documents from Novartis, from NPC, where the number 3 was identified as being the target number that put them in a position where they felt the risk was acceptable and that they could legitimately explain the speaker program as being a bona fide

program where scientific information was imparted to other physicians.
Q. Let me just back up and ask you a -- kind of a methodological question.
Your overall opinion is that NPC's compliance program was not effective as it related to speaker programs?
A. Uh-huh.
Q. Correct?
A. Right.
Q. And now we're walking through the seven elements of a compliance program, correct?
A. Right.
Q. Do you -- did you draw a conclusion about the effectiveness of each one of those elements?
A. I did, but there's a caveat. I looked at them sequentially, so I looked -- rather than breaking it down into individual elements at the outset, I looked at the speaker program across time and then went back and looked at the individual elements, speaker program compliance over time. So, yes.
Q. So the reason I ask is because on page

10 you say on the first paragraph, the second line, "NPC's minimum attendance policy was deficient," and then you explain why.
Is "deficient" just another word for saying "not effective"?
A. Yes, that was just the choice of the word that I used.
Q. Okay. If we look at the next paragraph you -- you talk about a development or developments in the -- in the policies as it relates to legitimate attendees.
Do you see that?
A. No, I -- where are you?
Q. In the next paragraph.
A. Uh-huh.
Q. "Prior to 2003, NPC had no requirement for a minimum number"?
A. Oh, okay. Uh-huh.
Q. Then, starting in 2003, there had to be at least three healthcare professionals?
A. Yes, sir.
Q. And the interpretation of healthcare professionals was left up to the sales force, you saw that?

A. Yes.
Q. And then in 2004, "healthcare professionals" was defined as those with prescribing rights, but the minimum requirement was loosened because -- by permitting speaker programs to proceed without three legitimate attendees if the sales rep had made a good faith effort to ensure minimum attendance. Do you see that?
A. Yes.
Q. And in your opinion, or are you expressing an opinion that there was something problematic about having that good faith exception?
A. No, I was just pointing out that factually that was what was occurring at that point in time. So the term "healthcare professionals" was further refined in the policies as those with prescribing rights. So I thought that was a positive effort.
"...the minimum required -- requirement was loosened by permitting Speaker Programs to proceed without the three legitimate attendees if the sales rep had made a 'good

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MS. JUDE: Objection to form.

A. No, I wouldn't say speaker programs specifically, but certainly promotion, promotion by physicians.

Q. And was there any written guidance that suggested that this was a risk, having, you know, prescribers of -- let me rephrase the question.

Was there any sort of written guidance that said, you know, there's a risk that, you know, colorectal surgeons are going to show up at Prozac speaker programs, you better watch out?

MS. JUDE: Objection.

Q. Because, you know, there's -- you know, those aren't the types of doctors that prescribe Prozac?

MS. JUDE: Objection to form.

Q. Do you remember any written guidance to that effect?

MS. JUDE: Same objection.

Q. Your counsel has an objection, but you can answer.

A. I don't recall the specific guidance.

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I know that at the Healthcare Compliance Association and American Health Law Association meetings that I attended, the idea that speaker programs and other meetings could be padded was very much discussed, and the idea of off-label and sort of benefits to being provided to physician speakers without a business justification was something that a lot of folks were talking about.

Q. Okay. Let's look at the next page in the final paragraph. In the last sentence, you say, "Until 2011, NPC's minimum attendance policy for Speaker Programs was not effective at managing the risk that promotional events could be used to provide payments to HCPs for illegitimate purposes."

Do you see that?

A. Yes.

Q. Earlier you testified that one of the questions you asked in an effectiveness analysis is, well, ultimately, what happened?

And is that what you're getting at here?

MS. JUDE: Objection to form.

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A. One second, please.

Q. Yeah.

A. Yeah, I think that -- I think that it was not an effective policy. It did not necessarily ensure the idea that speaker programs were going to be legitimate events that were used to educate other physicians about the benefits of a particular product, and so, yes, I don't think that the program was effective.

Q. And did you analyze any data about whether, you know, either non-prescribers of the drugs were showing up to pad numbers or that the minimum three wasn't being met?

A. I actually did, yes, I did look at data and looked at information not only from the third quarter 2008 audit that was conducted by Natalie Nelson-Ling -- Lang -- and David Hollasch, but I also looked at information from Mr. Goldberg, Richard Goldberg, who was another government expert, that showed that the minimum attendance policy was in fact an issue, so...

Q. Do you -- did you do anything to benchmark those data analyses against how other companies were doing at the time?

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A. I did not.

Q. Let's look at the next section, "Policy Regarding Guests"?

A. Excuse me. I'm sorry. I didn't mean to interrupt, but I believe that Julie Kane actually had done an analysis, and so I reviewed an e-mail that she provided I believe to the CEO analyzing the different policies that NPC had against other pharmaceutical companies.

I don't know what those pharmaceutical -- who those pharmaceutical companies were, and I certainly didn't check her data, but I used Novartis' own materials to that extent.

Q. Okay. To be clear, in your report you don't draw a conclusion as to whether Novartis' compliance program was more or less effective than other pharmaceutical companies' compliance programs during this time, do you?

A. I did not.

Q. Let's look at the next section, "Policies Regarding Guests."

A. Okay.

Q. You talk about the 2001 and 2003

guidelines contain no general prohibition against a guest or a spouse attending a speaker program, and there's evidence that NPC regularly allowed spouses to attend at that time.

Was there any guidance in 2001 prohibiting the attendance of a guest?

MS. JUDE: Objection to form.

Q. That you're aware of?

A. Yes, but again, I would refer to the HHS OIG 2003 Compliance Guidelines. I would also point out that the PhRMA Code at this -- back in 2002 stated that spouses and guests should not be -- should not attend.

Q. And did that guidance say they should not attend, or if they attend, it should be not be paid for by the company?

A. I don't believe that there's any business reason. I mean, if the reason that you're paying for the dinner and conferring a benefit on a physician is because it is an accommodation to that individual during the course of a business meeting where he or she is providing information about a particular drug and its benefits and safety issues to other

providers, there's no legitimate business reason for a spouse or a guest to be there. Therefore, I would say that that benefit triggers an anti-kickback violation -- or, sorry, anti-kickback risk.

Q. Okay. But you're not testifying here as a lawyer, correct?

A. I'm sorry?

Q. You're not testifying here as a lawyer?

A. No, sir.

Q. But my question was not about what you thought, but rather what the Pharma Guidance was in 2002?

A. Well, and --

Q. PhRMA Code guidance. Sorry.

A. The PhRMA Code guidance, I don't know whether it prohibited. I believe it prohibited. It said that spouses and guests should not be invited.

Q. Okay. Let's look at "Repeat Attendance," Section 3.

A. Okay.

Q. In the first sentence, "During the

Review Period, NPC's Compliance Policies failed to control for a serious AKS risk," and then you describe repeat attendance. Do you see that?

A. Yes.

Q. Are you familiar with any written guidance that says that repeat attendance is a serious AKS risk?

MS. JUDE: Objection to form.

A. Again, I would refer to the 2003 HHS OIG pharma manufacturers -- compliance guidance for pharma manufacturers, and also the PhRMA Code. I believe the 2009 code referred to occasional meals. And finally, to Novartis' own policy, NPC's own policies, that talked about occasional meals for healthcare providers and occasional dinners in the context of speaker programs.

Q. Did you ever advise your pharma clients about what "occasional" means for purposes of the PhRMA Code guidance?

A. Well, I certainly would not -- I'm sorry. Strike that.

Did I ever advise...

I -- I can -- I don't know if I ever

used the word "occasional." Sorry. I don't know if I ever used the word "occasional," but I can state that I have advised pharma and other entities who were providing -- who were in a position to provide benefits to healthcare providers that this is not something that should be done outside of the context of a business meeting on a regular basis.

So --

Q. Okay.

A. -- dinners and things of that nature, repeated events.

Q. Do you recall advising your clients about repeat attendance by doctors at the same program?

MS. JUDE: Objection to form.

Q. If you recall.

A. And I am concerned because I don't want to violate attorney-client privilege with respect to some of my service as a compliance officer and general counsel for Centra, so I'm just thinking about how to answer this question.

So, I'm sorry, can you repeat the question maybe?

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MR. GRUENSTEIN: I'm sorry. Can you read it back?

(Record read.)

Q. And I can limit it if it helps you on the attorney-client privilege to your consulting clients.

A. No, I don't recall providing that guidance.

Q. Do you recall the testimony of Natasha Nelson-Ling where she said -- she was asked about repeat attendance and said, you know, I -- I wish I had looked into it, but I didn't know that that was a risk until the U.S. Attorney's Office brought this case in 2000 -- whatever it was?

MS. JUDE: Objection.

Q. Do you recall that testimony?

A. Yes, I do.

Q. And what was your reaction to that, to reading that testimony?

A. I -- actually, I believed that Natalie Nelson-Ling and others in the compliance program had minimized this risk, and that was kind of surprising to me because there was a lot of

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material in the e-mails and in other documents, complaints, pharma -- CafePharma complaints, where people were talking about these repeated speaker events.

There was one particular instance involving a Dr. [redacted] where the investigation revealed that some of the doctors had gone to a -- a small group of doctors had gone to 23, 24, 25 events in a year, and that just did not make sense to me from an anti-kickback risk perspective.

Q. But just to be clear, that's based on Novartis internal materials, correct?

MS. JUDE: Objection to form.

A. I'm sorry, what is?

Q. What you just answered is you were surprised that compliance people didn't recognize the risk given all of the internal e-mails and findings that were going around Novartis, correct?

A. That's correct.

Q. But what I'm asking is, were you surprised that she hadn't heard, let's say, in a CIA or in other written guidance that repeat

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attendance was a serious AKS risk?

MS. JUDE: Objection. Misstates testimony.

A. I'm sorry, I have forgotten the question.

Q. I'll ask a -- I'll ask a slightly different question.

Was there any written guidance or indication in a CIA during the review period that repeat attendance by doctors at speaker programs was an AKS risk?

A. I don't know the answer to that question. I have not reviewed all of the CIAs. There were many, many during the time period, so...

Q. Let's look at the next page, 13.

A. Uh-huh.

Q. In the first full paragraph, you say, in the second sentence, "In my opinion, it is also clear from the materials that NPC was aware that repeat attendance prevented ser- -- presented serious compliance risks."

Do you see that?

A. Yes.

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Q. And what is your opinion there, if you could explain it?

A. Are you asking me to restate my opinion, sir?

Q. Well, I'm asking you to explain what you're saying. You say that NPC was aware.

Are you -- is that a conclusion about the company's knowledge?

MS. JUDE: Objection to form.

A. No, I'm actually -- what I was actually doing there is indicating a reference factually that -- referencing some of the information that I've talked about earlier that not only Natalie Nelson-Ling, but the "do's and don't's" document do not hold meetings on a recurring basis.

There was another one. Yes, it was Maria Woods when she was talking about -- and I think she had conducted an investigation and concluded that there wasn't sufficient information to substantiate the investigation as a compliance violation, but she said it appears that hosting the same individuals repeatedly at the same time at the same presentations may be

problematic because it creates the appearance of providing honoraria to speakers for illegitimate programs, kickback issues. So this was something that came up.

Also, they -- they did add to this FLM Dashboard information that, you know, to prevent repeat attendance because that would not comply with the occasional meals policy. So I think the occasional meals policy itself is a recognition that if you have repeated programs, same speakers, same drug, same attendees, then there may be an argument by some regulator or other person looking at the risk that this activity violates the Anti-Kickback Statute.

Q. Okay. But to be clear, I mean, you say, "In my opinion it is clear from the materials that NPC was aware."

It sounds like what you're saying now is, in your -- based on your review of all the documents and depositions cited in footnote 50, it seems that people at NPC were aware of this compliance risk; is that correct?

MS. JUDE: Objection to form.

A. I think that's right.

I'm sorry.

MS. JUDE: Go ahead.

A. I think that's right, yes.

Q. Let's go to "Venue," which is on page 14.

A. Okay.

Q. And this section is called 4, "Venue and Entertainment Policies."

A. Uh-huh.

Q. And what you -- in the first paragraph, you say, "NPC's Speaker Program policies did not properly manage the risk of conferring this benefit," which is -- the benefit that you're referring to is the -- the entertainment?

A. Uh-huh. Yes, sir.

Q. "...because entertainment was permitted for some types of events until 2008 and because sales representatives were allowed to apply their own judgment."

Do you see that?

A. Yes.

Q. And when you say "did not properly manage the risk," is that another way of saying

was ineffective?

A. I believe, yes, that is the same thing as saying it's not an effective compliance program.

Q. Okay. And then in the next paragraph, you say at the end of the paragraph that the decision to permit sales reps to exercise their judgment about proper -- about appropriate entertainment when their comp was based on volume of drugs prescribed by attending HCPs was a poor way to control anti-kickback risk.

Again, when you say "poor way to control anti-kickback risk," that's another way of saying ineffective, correct?

A. That's correct, uh-huh.

Q. You, in the next paragraph, you talk about how, in 2003, NPC's policy, these healthcare compliance guidelines, incorporated language from the PhRMA Code that promotional events should be held at "venues conducive to an exchange of medical information but also allowed modest entertainment such as golf."

Do you see that?

A. Yes.

Q. As you're measuring the effectiveness of the compliance program, does it fall on the positive side of the ledger that Novartis' policies were at least incorporating the language and the guidance from the PhRMA Code?

MS. JUDE: Objection to form.

A. I think it's positive to the extent that NPC was using language from the code and trying to conform its policies to the code, yes.

Q. Okay. And then you say, "Later NPC policies provided modest entertainment may be appropriate if approved by the Events Oversight Committee. The rationale supporting these exceptions to the no-entertainment rule is unclear."

Do you see that?

A. Yes.

Q. And when you say the rationale is unclear, do you mean that you weren't able to find anything in the record explaining why there might be exceptions approved?

A. Yes, that's correct. Mr. Putenis seemed to state that, in certain circumstances, entertainment would be appropriate and then in

guidelines contain no general prohibition against a guest or a spouse attending a speaker program, and there's evidence that NPC regularly allowed spouses to attend at that time.

Was there any guidance in 2001 prohibiting the attendance of a guest?

MS. JUDE: Objection to form.

Q. That you're aware of?

A. Yes, but again, I would refer to the HHS OIG 2003 Compliance Guidelines. I would also point out that the PhRMA Code at this -- back in 2002 stated that spouses and guests should not be -- should not attend.

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Review Period, NPC's Compliance Policies failed to control for a serious AKS risk," and then you describe repeat attendance. Do you see that?

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So --

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Q. Do you recall advising your clients about repeat attendance by doctors at the same program?

MS. JUDE: Objection to form.

Q. If you recall.

A. And I am concerned because I don't want to violate attorney-client privilege with respect to some of my service as a compliance officer and general counsel for Centra, so I'm just thinking about how to answer this question.

So, I'm sorry, can you repeat the question maybe?

A. Yes.

Q. And is it accurate to say that in 2010 Novartis changed the policy to reflect the development in 2009, which you cite in footnote 82?

MS. JUDE: Objection to form.

A. Yes, they did change the policy to reflect the fact that they were not counting the compensation paid towards speaker training, which was also to be counted not only, as I understand it, for state law reporting purposes, but also to get a fix internally in terms of compliance and finance on how much they were actually paying the speakers.

Q. Let's talk about the next Section 7, "Speaker Selection and Performance"?

A. Okay.

Q. In the second paragraph, you say, "In the absence of policies, the Compliance Department deferred to Sales on these matters."

Which is a reference to speaker selection, correct?

A. Yes, and also speaker performance.

Q. Okay. And I notice, despite your very

impressive number of footnotes, you don't have a footnote for that sentence, so I was wondering what are you relying on for that factual assertion?

A. Well, I would have to go back and go through all of the footnotes, which I don't think we need to do at this point, but to explain the -- the lack of effectiveness, the speaker policies did not address speaker selection until later on, and I think -- well, throughout the sales -- throughout the review period, the sales reps were permitted to nominate healthcare professionals to serve as speakers and that can be and was, in fact, a real benefit to some of the speakers?

(Knock on the door.)

A. Continue?

Q. Yes, please.

Maybe -- maybe I should ask another question because I think maybe you lost your train of thought, as did I.

A. Okay.

Q. Yeah, go ahead.

A. And also, with respect to performance.

The speaker performance issues were really left to the sales reps for throughout the bulk of the review period. They had to deal with speakers who weren't showing, speakers who deviated from the slides, speakers who did ten minutes.

It was really left up to them, which is a hard position to put them in given that their compensation is determined in part by how many speaker programs they had as well as the prescriptions.

Q. So then on the top of 20, you say, "In my opinion, sales associates should have been taken out of the speaker program -- speaker selection process entirely. HCP requests for speaking engagements should have been referred elsewhere in the organization."

Do you know whether other companies were doing that at this time?

A. I do not know the answer to that question.

Q. And then in the next paragraph, at the end of the paragraph, you say, "The best way to avoid this risk would have been for someone other than the sales associates to select

speakers."

When you say "the best way," that's like saying the best practice would have been?

A. Yes, I think so. It would have been a better practice and maybe the best practice to have an outside group, not necessarily the speakers, selecting -- I'm sorry, not necessarily the sales reps selecting the speakers.

That way you would have been able to make sure that you're meeting the criteria enumerated in the PhRMA Code and the HHS OIG Guidance, you know, having someone who is known in the field, someone who is experienced, someone who is a good speaker, who is reliable, who shows up.

Q. Okay. And do you know of any written guidance that says that that would be the best practice?

MS. JUDE: Objection to form.

A. No, I don't. Not off the top of my head, I don't.

Q. And going back to a question I've been asking you a lot, which is your opinions about

So, in light of those paragraphs, what did you mean when you said that Mr. Putenis didn't acknowledge this compliance risk?

A. Well, if you go back to page 211, Mr. Putenis also said -- stated that he understood, or, "We understood that the credibility of a speaker is enhanced if they have experience with our product, and that credibility is lost if they stand before an audience that have no experience in prescribing the product. So that is a relevant measure of the attractiveness of a particular person to serve in a speaker role for Novartis. It stands to reason that we would consider whether or not a doctor was a prescriber or -- whether a doctor was a prescriber or not when selecting them to serve on our speaker bureau."

So -- so then -- and then there were also a series of questions where the attorney who was doing the deposition asks about whether or not, as long as the speaker's reps -- I'm sorry. Strike that. As long as the sales reps are not selecting a speaker as an inducement, it's okay for a sales rep to select a speaker

simply because the speaker is a high-volume prescriber of Novartis drugs, and Mr. Putenis would not agree with that.

And then when they asked is it not okay, and he wouldn't agree with that either. So he also said high prescribing would never be the sole basis on which the person is selected, so -- and then the person who asked the question said: "Well, if it was, would that be a violation of Novartis' guidelines?" The answer was, "Not necessarily." "Under what circumstances would it not be a violation?" And again, Mr. Putenis said, "Because there are speakers that are preferable for us who have experience with the product, and that is a determination that's based on whether or not they prescribe."

Q. So would you agree with me that, in these five or six pages, he does say that it's okay to rely on the fact that a doctor has prescribed the drug to choose them to be a speaker?

A. Yes, he does say that, that experience with the product is something that they were

looking for.

Q. And he also says that people were told that they could not choose the speaker as a way of rewarding people for having been high prescribers, correct?

A. That's correct.

Q. But is what you're saying in the report that, based on your reading, it looks like he did not emphasize the compliance risk associated with rewarding high prescribers for prescribing by choosing them to be speakers?

A. That's correct. I did not feel like he recognized the risk, or if he recognized it, did not describe it adequately to the sales reps.

Q. Let's look at section B, Julie Kane.

A. Okay.

Q. And as a consultant, are you asked to consider the effectiveness of compliance officers?

A. To the extent that I'm looking at the effectiveness of a particular compliance program, and there are issues with respect to the leadership or competence or enthusiasm of

the compliance officer or the manner in which he or she presents the compliance communication message, yes, I do look at -- at the compliance officers and the department in general, departments in general.

Q. And presumably when you do that, you interview the compliance officer?

A. Yes, sir.

Q. And do you presumably interview the -- some of the people that report to the compliance officer?

A. Usually. Uh-huh.

Q. And you try to find out about the background and qualifications of the compliance officer?

A. Yes. Uh-huh.

Q. And you try to get a sense of how well they understand compliance principles?

A. Yes. Uh-huh.

Q. Do you have a sense of what Julie Kane's background was before she served in this role?

A. Yes, I did. I'm not sure that I can recall it at this point. I remember that she

VIRGINIA EVANS
AFTERNOON SESSION
THE VIDEOGRAPHER: The time is 2:14 p.m. We're back on the record, video number 4.
VIRGINIA EVANS, resumed and testified further as follows:
EXAMINATION BY (Cont'd.)
MR. GRUENSTEIN:
Q. So let's continue marching through your report, if you don't mind, and we'll look at Section VI, and let's just go to page 44.
A. Uh-huh. Okay.
Q. Just above B.
A. Yes, sir.
Q. It says, "An effective compliance program would have included an annual Compliance Risk Assessment followed by an annual Audit Work Plan to designed to address identified risks."
Do you see that?
A. Yes.
Q. And you've highlighted or you have italicized both instances of "annual" and you cite to the OIG guidance at 23741, do you see that?

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A. Yes.
Q. And you recognize that what the guidance says is regular compliance reviews, but in your experience, an annual compliance risk assessment and annual work plan are best practices, do you see that?
A. Yes.
Q. And as we spoke about earlier, just because something is less than best practices doesn't necessarily mean that it constitutes an ineffective control?
A. That's right.
Q. And you say that this is in your experience.
Is there any written guidance that I can look to that would say that an annual risk assessment or work plan is a best practice that you know of sitting here today?
A. I believe that there is a -- I'm sorry. I know that there is a workpaper or work document or guidance document on the HHS OIG website for boards of healthcare compliance of healthcare companies, and I believe that there is some information in that document that

VIRGINIA EVANS
relates to the board's duty to understand what the risks are in the company, and so in my experience dealing with boards, it's letting them know on an annual basis what the risks are and what the audit plan is going to be is the best practice.
Q. And do you know when that document was first published?
A. I don't.
Q. When was the last time you saw that document?
A. Maybe four months ago, five months ago.
Q. Okay. Let's go to the next Section, B.1.
A. Okay.
Q. "Compliance Auditing and Monitoring from 2002 to 2007."
In the first sentence you say, "NPC was aware that auditing and monitoring were important parts of an effective compliance program."
How do you know that NPC knew this?
A. Because from the very outset of the

VIRGINIA EVANS
review period, there were materials that talked about auditing and monitoring being something that NPC wanted to implement or would be implementing or, for example, Mr. Putenis stated that he became aware that it was something that was important sometime around 2003, 2004, but there was -- there was even an earlier -- there were even earlier documents showing that auditing and monitoring were understood to be part of an effective compliance program.
Q. And the fact that NPC was aware of this, how does that affect your opinion?
A. Well, if you don't know that a particular element or a particular behavior is necessary in order to determine whether or not your compliance program is effective, then you have a duty, I would think, as a compliance officer, a member of the Compliance Department, to, when you learn that that's -- that's something that's important, then you have a duty to find out more about it and implement it.
But auditing and monitoring was something that was there from the very beginning, and so I know that they were talking